



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Gevas et al.  
Serial No. : 10/762,226  
Filed : January 20, 2004

Art Unit : 1642  
Examiner : Susan Ungar, Ph.D.  
Cust. No. : 20985  
Conf. No. : 2197

Title : IMMUNOLOGICAL METHODS FOR THE TREATMENT OF  
GASTROINTESTINAL CANCER

**Mail Stop Amendment**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN  
ACCORDANCE WITH 37 C.F.R. §§ 1.97-1.98**

Because this Supplemental Information Disclosure Statement is filed after the receipt of a First Office Action on the Merits for the above-captioned application, a check for the filing fee of \$180.00 is enclosed. If no proper payment is enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 06-1050.

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§ 1.97-1.98. Forms PTO-1449 (3 pages) and copies of the cited non U.S. Patent documents are provided herewith in connection with the above-captioned application.

The documents cited on the Form PTO-1449 are in the English language. Hence, in accordance with the requirements of 37 C.F.R. § 1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

CERTIFICATE OF MAILING BY "EXPRESS MAIL"  
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I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR § 1.10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

Stephanie Seidman

Provided herewith is a copy of a Japanese Office Action, with informal translation, issued March 23, 2004, in connection with corresponding Japanese Patent Application No. 528702/1997 (Attorney Docket No. 17118-056JP1/ 2835JP), which is a national stage filing of International Patent Application No. PCT/US97/02029, which claims priority to U.S. Patent Provisional Application Serial No. 60/011,411. The instant application is a continuation of U.S. Patent Application Serial No. 08/798,423, which claims priority to U.S. Patent Provisional Application Serial No. 60/011,411. Hence the instant application and Japanese Patent Application No. 528702/1997 claim priority ultimately to the same application. In the Office Action, Examiner cites four documents: 1) Seva et al, "Growth-promoting effects of glycine-extended progastrin", Science 265:410-412 (1994); 2) Watson et al., "Anti-gastrin antibodies raised by gastrimmune inhibit growth of colorectal tumor AP5" Int. J. Cancer, 61(2):233-240 (1995); 3) WO 95/13297; 4) JP 4503072. Documents 1 and 2 have already been made of record in the instant application in an Information Disclosure Statement, supplied with Forms PTO-1449, filed 03/17/05. Documents 3 and 4 are being made of record in this Supplemental Information Disclosure Statement. Document 4 (JP 4503072) is in the Japanese language and is being supplied with an English language equivalent, WO 90/08774.

Provided herewith is a copy of a Japanese Office Action, with informal translation, issued May 16, 2006, in connection with corresponding Japanese Patent Application No. 528702/1997 (Attorney Docket No. 17118-056JP1/ 2835JP), which is a national stage filing of International Patent Application No. PCT/US97/02029, which claims priority to U.S. Patent Provisional Application Serial No. 60/011,411. The instant application is a continuation of U.S. Patent Application Serial No. 08/798,423, which claims priority to U.S. Patent Provisional Application Serial No. 60/011,411. Hence the instant application and Japanese Patent Application No. 528702/1997 claim priority ultimately to the same application. In the Office Action, Examiner cites one document: WO 95/13297. This document is being made of record in this Supplemental Information Disclosure Statement.

Applicant also makes known to the Examiner the following U.S. and international applications, which are commonly owned and/or have one or more inventors in common:

Applicant : Gevas *et al.*  
Serial No. : 10/762,226  
Filed : January 20, 2004

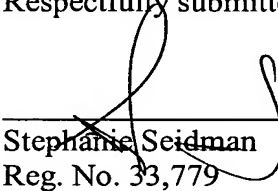
Attorney's Docket No.: 17118-056002 / 2835B  
Supplemental Information Disclosure Statement

<u>Serial No.</u>	<u>Filing Date</u>	<u>Docket No.</u>
10/762,226	01/20/04	17118-056002/ 2835B
10/235,236	09/04/02	17118-057002/ 2836B
10/323,692	12/19/02	17118-057003/ 2836C
10/098,690	03/15/02	17118-058002/ 2837B
10/829,137	04/21/04	17118-059US2/ 2838BUS
11/252,904	10/18/05	17118-060US3/ 2839CUS
10/192,257	07/09/02	17118-063001/ 2842
10/813,336	03/29/04	17118-064001/ 2843
11/360,378	02/22/06	n/a
PCT/US2005/10532	03/29/05	17118-064WO2/ 2843BPC
PCT/IB2006/001572	06/13/06	17118-068WO1/ 2847PC

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the documents or information, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97 (g) and (h), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56 (b) exists.

Applicant respectfully requests that the Examiner review the foregoing documents and make them of record in the file history of the above-captioned application.

Respectfully submitted,

  
Stephanie Seidman  
Reg. No. 33,779

Attorney's Docket No.: 17118-056002 / 2835B  
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Sheet 1 of 3

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 17118-056002/2835B	Application No. 10/762,226
		Applicant Gevas et al.	
		Filing Date January 20, 2004	Group Art Unit 1642

**Information Disclosure Statement  
by Applicant**  
(Use several sheets if necessary)

(37 CFR §1.98(b))

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	2002/0058040	05/16/02	Grimes et al.			
	AB	2002/0095028	7/18/2002	Grimes et al.			
	AC	2003/0021786	1/30/2003	Gevas et al.			
	AD	2003/0068326	4/10/2003	Gevas et al.			
	AE	2003/0086941	5/8/2003	Michaeli et al.			
	AF	2003/0091574	5/15/2003	Gevas et al.			
	AG	2004/0001842	1/1/2004	Michaeli et al.			
	AH	2005/0069966	3/31/2005	Grimes et al.			
	AI	2005/0187152	8/25/2005	Gevas et al.			
	AJ	2006/0020119	1/26/2006	Grimes et al.			
	AK	2006/0039911	2/23/2006	Gevas et al.			
	AL	2006/0140962	6/29/2006	Gevas et al.			
	AM	5,688,506	11/18/97	Grimes et al.			
	AN	6,169,173	01/02/01	Wank			
	AO	6,191,290	02/20/01	Safavy			
	AP	6,303,123	10/16/01	Grimes et al.			
	AQ	6,359,114	3/19/2002	Grimes et al.			

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AR	90/08774	08/09/90	PCT				
	AS	95/13297	05/18/95	PCT				
	AT	98/51337	11/19/98	PCT				
	AU	99/59612	11/25/99	PCT				
	AV	99/59628	11/25/99	PCT				
	AW	02/076499	10/03/02	PCT				

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Disclosure Form (PTO-1449)

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 17118-056002/2835B	Application No. 10/762,226
<b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Gevas et al.	
		Filing Date January 20, 2004	Group Art Unit 1642

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	AX	Aphthon Biopharma <i>BIO2005 Presentation</i> , June 19-22, Philadelphia, PA (2005), 26 pages
	AY	Baba <i>et al.</i> , "Glycine-extended gastrin induces matrix metalloproteinase-1- and 3-mediated invasion of human colon cancer cells through type I collagen gel and Matrigel" <i>Int. J. Cancer</i> 111(1):23-31 (2004)
	AZ	Berd <i>et al.</i> , "Induction of Cell-mediated Immunity to Autologous Melanoma Cells and Regression of Metastases after Treatment with a Melanoma Cell Vaccine Preceded by Cyclophosphamide," <i>Cancer Res.</i> 46:2572-2577 (1986)
	BA	Buchan <i>et al.</i> , "Regulatory peptides in Barrett's oesophagus," <i>J. Pathol.</i> 146(3):227-234 (1985)
	BB	Caplin <i>et al.</i> , "Expression and processing of gastrin in hepatocellular carcinoma, fibromellar carcinoma and cholangiocarcinoma," <i>J. Hepatology</i> 30(3):519-526 (1999)
	BC	Caplin <i>et al.</i> , "Effect of gastrin and anti-gastrin antibodies on proliferation of hepatocyte cell lines" <i>Digestive Diseases and Sciences</i> 46(7):1356-1366 (2001)
	BD	Caplin <i>et al.</i> , "Demonstration of new sites of expression of the CCK-B/gastrin receptor in pancreatic acinar AR42J cells using immunoelectron microscopy" <i>Regulatory Peptides</i> 84(1-3):81-89 (1999)
	BE	Clerc <i>et al.</i> , "Differential Expression of the CCK-A and CCK-B/Gastrin Receptor Genes in Human Cancers of the Esophagus, Stomach, and Colon," <i>Int. J. Cancer</i> 72:931-936 (1997)
	BF	"Gastrin 17 vaccine-Aphthon: Anti-gastrin 17 immunogen, G17DT," <i>Biodrugs</i> 17(3):223-225 (2003)
	BG	Gocyk <i>et al.</i> , "Helicobacter pylori, gastrin and cyclooxygenase-2 in lung cancer," <i>Med. Sci. Monit.</i> 6(6):1085-1092 (2000)
	BH	Gura, T., "Systems for Identifying New Drugs Are Often Faulty," <i>Science</i> , 278(5340):1041-1042 (1997)
	BI	Harris <i>et al.</i> , "An Antiapoptotic Role for Gastrin and the Gastrin/CCK-2 Receptor in Barrett's Esophagus," <i>Cancer Res.</i> 64:1915-1919 (2004)
	BJ	Jain, R.K., "Barriers to drug delivery in solid tumors," <i>Sci. Am.</i> 171(1):58-65 (1994)
	BK	Kelley <i>et al.</i> , "Antitumor activity of a monoclonal antibody directed against gastrin-releasing peptide in patients with small cell lung cancer," <i>Chest</i> , 112:256-261 (1997)
	BL	Koh <i>et al.</i> , "Glycine-Extended Gastrin Promotes the Growth of Lung Cancer," <i>Cancer Res.</i> 64:196-201 (2004)
	BM	McWilliams <i>et al.</i> , "Antibodies raised against the extracellular tail of the CCKB/gastrin receptor inhibit gastrin-stimulated signaling," <i>Regulatory Peptides</i> 99(2-3):157-161 (2001)
	BN	MSNBC News Services, "Mixed results on new cancer drug," November 9, 2000 (4 pages)
	BO	Moody <i>et al.</i> , "GRP Receptors Are Present in Non Small Cell Lung Cancer Cells," <i>J. Cell Biochem. Suppl.</i> , 24:247-256 (1996)
	BP	Mulholland <i>et al.</i> "Elevated Gastric Acid Secretion in Patients with Barrett's Metaplastic Epithelium," <i>Dig Dis. Sci.</i> 34(9):1329-1334 (1989)
	BQ	Osband, M.E. and S. Ross, "Problems in the investigational study and clinical use of cancer immunotherapy," <i>Immunology Today</i> , 11:193-195 (1990)
	BR	Pannequin <i>et al.</i> , "Divergent roles for ferric ions in the biological activity of amidated and non-amidated gastrins," <i>J. Endocrinol.</i> 181(2):315-325

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 17118-056002/2835B	Application No. 10/762,226
<b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Gevas et al.	
		Filing Date January 20, 2004	Group Art Unit 1642

**Other Documents (include Author, Title, Date, and Place of Publication)**

Examiner Initial	Desig. ID	Document
	BS	Rehfeld, J.F., "Three components of gastrin in human serum," <i>Biochim. Biophys. Acta.</i> , 285:364-372 (1972)
	BT	Smith <i>et al.</i> , "Gastrin and colorectal cancer," <i>Alimentary Pharmacology &amp; Therapeutics</i> 14:1231-1247 (2000)
	BU	Smith <i>et al.</i> , "Gastrin and gastrin receptor activation: an early event in the adenoma-carcinoma sequence," <i>Gut</i> 47(6):820-824 (2000)
	BV	Smith <i>et al.</i> , "Gastrin may have an autocrine/paracrine role in Barrett's oesophagus and oesophageal adenocarcinoma," <i>Br. J. Surgery</i> 84:706-707 (1996).
	BW	Smith <i>et al.</i> , "Phase I/II study of G17-DT, an anti-gastrin immunogen, in advanced colorectal cancer," <i>Clin. Cancer Res.</i> 6(12):4719-4724 (2000)
	BX	Thorndyke, M. and G.J. Dockray, "Identification and localization of material with gastrin-like immunoreactivity in the neutral ganglion of a photochordate, <i>Ciona intestinalis</i> ," <i>Regulatory Peptides</i> 16:269-279 (1986)
	BY	Torosian <i>et al.</i> , "Colon carcinoma metastatic to thigh - an unusual site of metastasis. Report of a case," <i>Diseases of the Colon and Rectum</i> 30(10):805-808 (1987)
	BZ	Watson <i>et al.</i> , "Inhibitory effects of the gastrin receptor antagonist (L-365,260) on gastrointestinal tumor cells," <i>Cancer</i> 68(6):1255-1260 (1991)
	CA	Watson <i>et al.</i> , "Pre-clinical evaluation of the Gastrimmune immunogen alone and in combination with 5-fluorouracil/leucovorin in a rat colorectal cancer model," <i>Int. J. Cancer</i> 75(6):873-877 (1998)
	CB	Watson <i>et al.</i> , "Expression of gastrin/CCKB receptor isoforms in gastrointestinal tumor cells: Relationship to gastrin secretion," <i>Scientific Proceedings of the 88th Annual Meeting of the American Association for Cancer Research</i> , April 12-16, 1997, San Diego, California, Volume 38(0):116 (Abst. # 773) (1997)
	CC	Watson <i>et al.</i> , "Antiserum raised against an Epitope of the Cholecystokinin B/gastrin receptor Inhibits Hepatic Invasion of a Human Colon Tumor," <i>Cancer Res.</i> 60(20):5902-5907 (2000)
	CD	Watson <i>et al.</i> , "Gastrin antagonists and gastrointestinal tumors," <i>Expert. Opin. Invest. Drugs</i> 4(12):1253-1266 (1995)
	CE	Watson <i>et al.</i> , "Antibodies Raised by Gastrimmune Inhibit the Spontaneous Metastasis of a Human Colorectal Tumour, AP5LV," <i>European J. Cancer</i> 35(8):1286-1291 (1999)
	CF	Watson <i>et al.</i> , "A comparison of an anti-gastrin antibody and cytotoxic drugs in the therapy of human gastric ascites in SCID mice," <i>Int. J. Cancer</i> 81(2):248-254 (1999)
	CG	Watson <i>et al.</i> , "G17DT-A new weapon in the therapeutic armoury for gastrointestinal malignancy," <i>Expert Opin. Biol. Ther.</i> 1(2):309-317 (2001)
	CH	Watson <i>et al.</i> , "Inhibition of gastrin-stimulated growth of gastrointestinal tumour cells by octreotide and the gastrin/cholecystokinin receptor antagonists, proglumide and lorglumide," <i>Eur. J. Cancer</i> 28A(8-9):1462-1467 (1992)
	CI	Watson <i>et al.</i> , "The in vitro growth response of primary human colorectal and gastric cancer cells to gastrin," <i>Int. J. Cancer</i> 43:692-696 (1989)
	CJ	Watson <i>et al.</i> , "Therapeutic effect of the gastrin receptor antagonist, CR2093 on gastrointestinal tumour cell growth," <i>British Journal of Cancer</i> 65(6):879-883 (1992)
	CK	Weiner, L.M., "An Overview of Monoclonal Antibody Therapy of Cancer," <i>Seminars in Oncology</i> 26(4)(Supp. 12):41-50 (1999)

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